

**Amendments to the Claims:**

This listing of claims will replace all prior versions and listing of claims in the application.

**Listing of Claims:**

Claims 1-105 (canceled)

Claim 106 (previously presented): A method for inducing an antigen-specific immune response in a subject comprising:

- a) pretreating an area of the skin of said subject, wherein pretreating comprises applying means for enhancing penetration and/or barrier disruption of the skin; and
  - b) applying a formulation to said pretreated area, wherein said formulation comprises:
    - 1) at least one antigen in an amount effective to induce an antigen-specific immune response;
    - 2) at least one adjuvant present in an amount effective to induce said immune response to said at least one antigen; and,
    - 3) a pharmaceutically acceptable carrier;
- wherein said pretreating enhances said immune response.

Claim 107 (previously presented): The method of claim 106, wherein said pretreating comprises applying to the skin at least a chemical means, a physical means, a mechanical means, a hydration means, or a combination thereof.

Claim 108 (previously presented): The method of claim 107, wherein said area of the skin comprises an outermost layer and said pretreating disrupts only the outermost layer of said area of the skin.

Claim 109 (previously presented): The method of claim 106, wherein said pretreating comprises applying at least one chemical to said area of the skin.

Claim 110 (previously presented): The method of claim 106, wherein said pretreating comprises applying to the skin an alcohol, an acetone, a detergent, a depilatory agent, a keratinolytic formulation, or a combination thereof.

Claim 111 (previously presented): The method of claim 106, wherein said pretreating comprises applying a device.

Claim 112 (previously presented): The method of claim 111, wherein said device is selected from the group consisting of a propellant device, a device comprising tines, a device comprising microneedles, a device comprising a tine disk, a tape stripping device, a gas powered gun, a swab, an emery board, an abrasive pad, an electroporation device, an ultrasound device, and an iontophoresis device.

Claim 113 (previously presented): The method of claim 111, wherein a patch comprises said device.

Claim 114 (previously presented): The method of claim 106, wherein said antigen is derived from a pathogen.

Claim 115 (previously presented): The method of claim 114, wherein said antigen is derived from an influenza virus

Claim 116 (previously presented): The method of claim 115, wherein said antigen is hemagglutinin A.

Claim 117 (previously presented): The method of claim 114, wherein said antigen is derived from a bacteria.

Claim 118 (previously presented): The method of claim 117, wherein said antigen is *E. coli* heat-labile enterotoxin (LT).

Claim 119 (previously presented): The method of claim 106, wherein said adjuvant comprises a molecule selected from the group consisting of a bacterial ADP-ribosylating exotoxin (bARE), a binding B subunit of a bARE, a toxoid of a bARE, a genetically altered bARE, and a genetically detoxified mutant of a bARE.

Claim 120 (previously presented): The method of claim 106, wherein said antigen and said adjuvant are the same molecule.

Claim 121 (previously presented): The method of claim 120, wherein the molecule is LT.

Claim 122 (previously presented): The method of 121, wherein LT is applied using a patch.

Claim 123 (previously presented): The method of claim 106, wherein the formulation is applied using a patch.

Claim 124 (previously presented): A method for inducing an antigen-specific immune response in a subject comprising concurrently

- a) treating an area of the skin of said subject; and
- b) applying a formulation to said treated area, wherein said formulation comprises:
  - 1) at least one antigen in an amount effective to induce an antigen-specific

immune response;

2) at least one adjuvant present in an amount effective to induce said immune response to said at least one antigen; and,

3) a pharmaceutically acceptable carrier;

wherein said treating enhances said immune response.

Claim 125 (previously presented): The method of claim 124, wherein said treating comprises applying to the skin at least a chemical means, a physical means, a mechanical means, a hydration means, or a combination thereof.

Claim 126 (previously presented): The method of claim 125, wherein said area of the skin comprises an outermost layer and said treating disrupts only the outermost layer of said area of the skin.

Claim 127 (previously presented): The method of claim 124, wherein said treating comprises applying at least one chemical to said area of the skin.

Claim 128 (previously presented): The method of claim 124, wherein said treating comprises applying to the skin an alcohol, an acetone, a detergent, a depilatory agent, a keratinolytic formulation, or a combination thereof.

Claim 129 (previously presented): The method of claim 124, wherein said treating comprises applying a device.

Claim 130 (previously presented): The method of claim 129, wherein said device is selected from the group consisting of a propellant device, a device comprising tines, a device comprising microneedles, a device comprising a tine disk, a tape stripping device, a gas powered gun, a swab, an emery board, an abrasive pad, an electroporation device, an ultrasound device,

and an iontophoresis device.

Claim 131 (previously presented): The method of claim 129, wherein a patch comprises said device.

Claim 132 (previously presented): The method of claim 124, wherein said antigen is derived from a pathogen.

Claim 133 (previously presented): The method of claim 132, wherein said antigen is derived from an influenza virus

Claim 134 (previously presented): The method of claim 133, wherein said antigen is hemagglutinin A.

Claim 135 (previously presented): The method of claim 132, wherein said antigen is derived from a bacteria.

Claim 136 (previously presented): The method of claim 135, wherein said antigen is *E. coli* heat-labile enterotoxin (LT).

Claim 137 (previously presented): The method of claim 124, wherein said adjuvant comprises a molecule selected from the group consisting of a bacterial ADP-ribosylating exotoxin (bARE), a binding B subunit of a bARE, a toxoid of a bARE, a genetically altered bARE, and a genetically detoxified mutant of a bARE.

Claim 138 (previously presented): The method of claim 124, wherein said antigen and said adjuvant are the same molecule.

Claim 139 (previously presented): The method of claim 138, wherein the molecule is LT.

Claim 140 (previously presented): The method of 139, wherein LT is applied using a patch.

Claim 141 (previously presented): The method of claim 124, wherein the formulation is applied using a patch.

Claim 142 (previously): A method for inducing an antigen-specific immune response in a subject comprising:

- a) delivering parenterally a first formulation comprising at least one antigen to said subject;
- b) treating an area of the skin of said subject, wherein treating comprises applying means for enhancing penetration and/or barrier disruption of the skin to enhance said immune response; and
- c) applying a second formulation comprising at least one adjuvant to the area of the skin, thereby inducing an antigen-specific immune response.

Claim 143 (previously presented): The method of claim 142, wherein said treating comprises applying to the skin at least a chemical means, a physical means, a mechanical means, a hydration means, or a combination thereof.

Claim 144 (previously presented): The method of claim 142, wherein said area of the skin comprises an outermost layer and said treating disrupts only the outermost layer of said area of the skin.

Claim 145 (previously presented): The method of claim 142, wherein said treating

comprises applying at least one chemical to said area of the skin.

Claim 146 (previously presented): The method of claim 142, wherein said treating comprises applying to the skin an alcohol, an acetone, a detergent, a depilatory agent, a keratinolytic formulation, or a combination thereof.

Claim 147 (previously presented): The method of claim 142, wherein said treating comprises applying a device.

Claim 148 (previously presented): The method of claim 147, wherein said device is selected from the group consisting of a propellant device, a device comprising tines, a device comprising microneedles, a device comprising a tine disk, a tape stripping device, a gas powered gun, a swab, an emery board, an abrasive pad, an electroporation device, an ultrasound device, and an iontophoresis device.

Claim 149 (previously presented): The method of claim 147, wherein a patch comprises said device.

Claim 150 (previously presented): The method of claim 142, wherein said antigen is derived from a pathogen.

Claim 151 (previously presented): The method of claim 150, wherein said antigen is derived from an influenza virus

Claim 152 (previously presented): The method of claim 151, wherein said antigen is hemagglutinin A.

Claim 153 (previously presented): The method of claim 150, wherein said antigen is

derived from a bacteria.

Claim 154 (previously presented): The method of claim 153, wherein said antigen is *E. coli* heat-labile enterotoxin (LT).

Claim 155 (previously presented): The method of claim 142, wherein said adjuvant comprises a molecule selected from the group consisting of a bacterial ADP-ribosylating exotoxin (bARE), a binding B subunit of a bARE, a toxoid of a bARE, a genetically altered bARE, and a genetically detoxified mutant of a bARE.

Claim 156 (previously presented): The method of claim 142, wherein said antigen and said adjuvant are the same molecule.

Claim 157 (previously presented): The method of claim 156, wherein the molecule is LT.

Claim 158 (previously presented): The method of 157, wherein LT is applied using a patch.

Claim 159 (previously presented): The method of claim 142, wherein the formulation is applied using a patch.

Claim 160 (canceled)

Claim 161 (previously presented): The method of claim 142, wherein the first formulation is administered subcutaneously, intradermally, or intramuscularly.